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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,894	01/23/2004	Michel Pairet	1/1193-2-C2	7787

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EXAMINER	
RAE, CHARLESWORTH E	
ART UNIT	**PAPER NUMBER**
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,894	PAIRET ET AL.	
	Examiner	Art Unit	
	Charleswort Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *15-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 15-26 are currently pending and are the subject of this Office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 15-23, drawn to a propellant-free inhalable solution or suspension, classified as class 514, subclass 237.2, 253.01, 316, 319+. If this group is elected, then the below Summarized Species Election requirement is also required.

II. Claim 24-26, drawn to a method for treatment of chronic obstructive pulmonary disease (COPD), classified as class 514, subclass 237.2. If this group is elected, then the below Summarized Species Election requirement is also required.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, invention II may be practiced by using another materially different product. For example, invention II may be practiced using oral sympathomimetics.

Because inventions I-II are independent or distinct for the reasons given above, coupled with the fact that a search is required for each group, restriction for examination purposes is proper. While inventions I-II can be identically classified under U.S. Patent Classification guidelines, to search them together would present an undue search burden on the Examiner due to the extensive databases of patent and non-patent literature that would have to be

searched in view of the multiplicity of different chemical compounds and divergent subject matter encompassed by these different groups. Thus, Groups I-II have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Election of Species regarding Groups I-II

This application contains claims directed to more than one species of the generic inventions that would require an unduly extensive and burdensome search by the examiner if all the claimed species were examined together.

The generic inventions encompass multiple species of chemical compounds. Each chemical compound represents a different chemical entity and would reasonably exhibit different pharmaceutical characteristics when suspended in an inhalable suspension or dissolved in an inhalable solution. The pharmaceutical characteristics of these chemical compounds would reasonably vary depending on the salt form of tiotropium, the presence of additional active substances, and the solvent/solvents used in the formulation. Similarly, the variablitiy in the pharmaceutical characteristics of these formulations would reasonably influence the amount of active agent(s) delivered to the target site, as well as treatment effects contemplated in practicing the instant inventions. Thus, an undue search burden would be created if all of the formulation species were examined together.

In view of the burden that would be created if all of these species were examined together, applicant is required to elect for examination purposes the following:

i) a single specific disclosed inhalable formulation, wherein:

a) the **active salt of tiotropium** is specifically specified e.g. tiotropium bromide,

b) the **NK1-receptor antagonist**(s) is/are specifically specified e.g. (S)-N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]2-[4-(2-hydroxymethyl-ethylamino) piperidin-1-yl]-N-methyl-2-phenylacetamide,

c) the μg weight ratio of the tiotropium salt to the NK1-receptor antagonist e.g. specified e.g. 12 μg tiotropium salt to 700 μg (S)-N-[2-(3,5-bis-trifluoromethyl phenyl)-ethyl]2-[4-(2-hydroxymethyl-ethylamino) piperidin-1-yl]-N-methyl-2-phenylacetamide

d) the specific solvent/solvent mixture e.g. ethanol.

Additional Election of Species regarding Groups I-IV

The generic inventions also encompass multiple species of chronic obstructive pulmonary disease (COPD) which represent separate and distinct pathological characteristics e.g. asthma, chronic bronchitis, and emphysema; these species have also acquired separate status in the art. Further, the treatments effects contemplated in practicing the formulations encompassed by the instant inventions would reasonably vary depending on the particular targeted species. Thus, an undue search burden would be created if all these species were searched together.

Applicant is therefore required to elect a single specific COPD species for examination purposes e.g. asthma

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 15, 24, and 25 are considered generic to the above listed species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have

any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

6 April 2007
CER

BRIAN-YONG S. KWON
PRIMARY EXAMINER